SECTION 5 **510(k) SUMMARY**

MAY 13 2011

**Date of Submission**: May 12, 2011

**Official Contact**:

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**Proprietary Name**: VR Medical Enteral Oral Syringe

**Common/ Usual Name**: Gastrointestinal tubes and accessories

**Classification Reference**: 21 CFR 876.5980

**Product Code**: FPD

**Predicate Devices**: Phillips Children's Medical Venture Oral/ Enteral Syringe (K100099)

Wei Gao Group Medical Syringe (K072739)

**Indication for Use:**
The Oral Enteral Syringe is intended for the delivery of liquid medication, formula and breast milk.

**Patient Population/ Environment of Use:**
The patient population is for neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral Enteral Syringes are disposable and for single patient use only.

**Substantial Equivalence**
The VR Medical Oral Enteral Syringe is substantially equivalent to commercially available oral enteral syringes. The VR Medical Oral Enteral Syringe's indication for use and FDA Product Code/ Classification Codes are identical to the Phillips Children's Medical Venture Oral/ Enteral Syringe (K100099) and thus is substantially equivalent.

The VR Medical Oral Enteral Syringe components' biocompatible materials are either identical to, or substantially equivalent to, the Phillips Children's Medical Venture Oral/ Enteral Syringe (K100099) and the Wei Gao Group Medical Syringe (K072739).

The VR Medical Oral Enteral Syringe's Technical Characteristics, Packaging and Ethylene Oxide Sterilization Characteristics, as well as Labeling Characteristics, are

substantially equivalent to both the Phillips Children's Medical Venture Oral/ Enteral Syringe (K100099) and the Wei Gao Group Medical Syringe (K072739).

The VR Medical Oral Enteral Syringe and components successfully completed in-vitro testing that demonstrated that the device functions according to its specifications and is thus substantially equivalent in function to both the Phillips Children's Medical Venture Oral/ Enteral Syringe (K100099) and the Wei Gao Group Medical Syringe (K072739).

Design verification tests were performed on the Oral Enteral Syringe as a result of the risk analysis and product requirements. The following tests and analysis were conducted demonstrating the VR Medical Oral Enteral Syringe met the acceptance criteria.

| Specific Test | Test Model | Justification |
|---|---|---|
| Syringe Tip Tensile Test | VR Medical Syringe and Phillips Syringe (K100099) tested | Actual proposed device and predicate (K100099) tested |
| Syringe Liquid Leakage Test | VR Medical Syringe tested | Actual proposed device tested |
| Volume Measurement Accuracy Testing (manual. ISO 7886-1 and syringe pump, ISO 7886-2) | VR Medical Syringe and Phillips Syringe (K100099) tested | Actual proposed device and predicate (K100099) tested |
| ISO 7886-1 requirements (excluding tip requirements) | VR Medical Syringe tested | Actual proposed device tested |
| Size and Material Inspection | VR Medical Syringe tested | Actual proposed device tested |
| Biocompatibility Analysis (Syringe materials) | Referenced to predicate | VR Medical device component materials and processes identical to referenced predicate (except orange colorant) |
| Biocompatibility Analysis (Orange colorant) | Referenced to 21 CFR 178.3297 | These colorants are cleared (or FDA listed) as food contact substance |
| Sterilization Related Testing | VR Medical Syringe tested | Actual proposed device tested |
| Storage and Shelf Life Testing (accelerated-time aging) | VR Medical Syringe tested | Actual proposed package and device tested |
| Storage and Shelf Life Testing (real time aging) | Referenced to predicate | VR Medical device packaging identical to referenced predicate device package/ process |
| Package Related Testing | VR Medical Syringe tested | Actual proposed device tested |
| ISO 80369-1 requirements | VR Medical Syringe tested | Actual proposed device tested |

**Device Description**

The Oral Enteral Syringe is intended as a single use, sterile, device for the delivery of liquid medication, formula and breast milk. The Oral Enteral Syringe comes in multiple volume sizes ranging from 1cc to 60cc [e.g., 1cc, 3cc, 5cc, 10cc, 20cc, 30cc and 60cc]. The VR Medical Oral Enteral Syringe, as well as the predicate device [Phillips Children's Medical Venture Oral/ Enteral Syringe (K100099)] has 'labeling' on the device itself, i.e., highly visible labeling on side of barrel marked ORAL/ENTERAL ONLY, and the utilization of bright orange colorant for the plunger and cap that easily distinguishes the syringe for feeding and not other uses.

The Oral Enteral Syringe incorporates safety connectors which eliminate the risk of IV administration through the feeding tube, i.e., the safety connectors will not mate with Luer Lock or Leur slip fittings. Analytical comparisons and lab testing of the VR Medical device tip's dimensions to the others devices listed in the ISO 80369-1 allow the conclusions that:

- The VR Medical and Phillips Children's device tips are substantially equivalent.
- The VR Medical device tip is not substantially equivalent to the Wei Gao Group Syringe tip
- The VR Medical device tip is not compliant with the ISO 594 standard's tip requirements.
- The VR Medical device tip is not compliant with other small-bore connectors listed in the ISO 80369-1 except Enteral feeding tips.

Syringe tip analytical engineering evaluation again demonstrates that the width (outside diameter, OD) of the VR Medical syringe tip is larger than the ISO 594 Female Luer Connector standard IV connector inner diameter (ID) dimensions [4.27-4.31 mm]. Thus, the VR Medical syringe tip cannot physically fit into an ISO 594 rigid female Leur connector and does not conform to the ISO 594 standard's requirements.

While VR Medical has searched for an applicable standard for the dimensions of feeding tubes' rigid female connectors, none were found. However, in order for hospitals to purchase feeding tubes from a variety of manufactures and be assured that these different devices will all be compatible with the hospitals' existing equipment, the industry utilizes the same female connector ID dimensions, e.g., a 'common use'. To ensure these 'common use' dimensions, the VR Medical syringe was evaluated against three different commercially available feeding tubes in relation to their rigid female connectors.

These analyses demonstrated that the VR Medical Oral Enteral Syringe's tip dimensions fit well within the female connector of commercially available feeding tubes, e.g., the MPS Acacia Enteral Feeding Tube's female connector (K080328), the AMERITUS Enteral Feeding Tube's female connector (K100526) and the NeoMed Enteral Only Extension Set's female connector (K100288).

The VR Medical Oral Enteral Syringe design incorporates various components, e.g., barrels, plungers, caps and end caps, which are comprised of commercially available materials with demonstrated acceptable biocompatibility, as listed below:

| Syringe Component | Component Material |
|---|---|
| Barrel Material | Polypropylene 370Y |
| Piston Material | Thermoplastic Elastomer IR307 |
| Plunger Material | Polypropylene 370Y |
| Plunger Colorant | Orange Pigment* |
| Cap Material | Polypropylene 370Y |
| Cap Colorant | Orange Pigment (P21024) |
| Barrel Gradation Ink | PPE Ink Series (on outside of barrel) |
| Nozzle Material | Polypropylene 370Y (molded with barrel) |
| * It is important to note that the US FDA has already concluded in 21 CFR 178.3297 that these colorants are cleared (or FDA listed) as food contact substance, e.g., acceptable use as an indirect food additive for use as a component of materials used in manufacturing, packaging, transporting or holding food. | |

The Oral Enteral Syringe does not contain natural rubber latex, DEHP, or BPA.

**Conclusion**

The conclusions drawn from the actual conducted (as well as the referenced) analytical engineering evaluations, the nonclinical tests and the commercial use of similar and predicate devices, demonstrate that the VR Medical Oral Enteral Syringe is as safe, as effective and performs at least as safely and effectively as the legally marketed (predicate) devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

VR Medical Technology Co.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLD
1394 25th Street NW
BUFFALO MN 55313

MAY 13 2011

Re: K110853
Trade/Device Name: VR Medical Oral Enteral Syringe
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: April 26, 2011
Received: April 27, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 **INDICATION FOR USE STATEMENT**



**510(k) Number (if known):** K110853

**Device Name:** VR Medical Oral Enteral Syringe

**Indication for Use:**
The Oral Enteral Syringe is intended for the delivery of liquid medication, formula and breast milk.

**Patient Population/ Environment of Use:**
The patient population is for neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral Enteral Syringes are disposable and for single patient use only.

Prescription Use ___X____ AND/ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110853